K131138

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MEDICAL REGISTRATION

SECTION 5 - 510(k) Summary (21 CFR 807.92)

510(k) Number K_____

SEP 09 2013

1	Submission Owner	Respire Medical® LLC 18 Bridge St., Ste. 4J Brooklyn, 11201 NY Phone 718-643-7326 Fax 718-643-7322		
2	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22817 Ventura blvd. #161 Woodland Hills, CA 91364, USA Phone 213-787-3026 Fax 213-447-5297 Web www.sterlingmedicalregistration.com		
3	Submission Date	April 2013		
4	Device Trade Name	Respire Pink Series- Herbst		
5	Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)		
6	Classification	Device Name	:	Device, Anti-Snoring
		Product Code	:	LRK
		Regulation No	:	872.5570
		Class	:	II
		Panel	:	Dental
7	Reason for the Premarket Notification Submission		:	New Device

8 Identification of Legally Marketed Predicate Devices :

- Respire Pink Series - Herbst is substantially equivalent to Respire Blue Series K111207 ; SUAD K023836 in terms of intended use, indication for use, technological characteristics, performance and user interface. The predicate devices are Class II medical devices.

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9 Device Description :

Respire Pink Series - Herbst is a customized device for each patient which consists of two dental plates, upper and lower, made of Acrylic.

The Respire Pink Series – Herbst is a mandibular advancement splint that holds the jaw in a forward position to help keep the tongue and supporting tissues in a position to help maintain an open airway, which in turn helps in the treatment of snoring and mild to moderate obstructive sleep apnea.

The Herbst hardware on the side of the devices allow the patient to move forward and left and right, but not backwards. These movements give the patient some freedom to move which is important for their comfort and overall success of the device.

The upper and lower components are connected by an adjustable hinge, thus patient can open and close while wearing the appliances.

Respire Pink Series - Herbst are offered in two options: (1) Hard/Soft which has a dual laminate layer that provides a soft layer on the tooth surface (2) Hard devices which are all acrylic and retained with ball clasps, this allows the device to be tightened if it becomes loose.

10 Intended use :

- The Respire Pink Series - Herbst is indicated to treat mild to moderate OSA.

11 Performance Standards or Special Controls :

- Recognized Consensus Standard: ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

12 Substantial Equivalence :

Substantial Equivalent Table	**Respire Blue Series (Hard/Soft Surface)**	**Respire Blue Series (Hard Surface)**	**Respire Pink Series - Herbst**	**SUAD**
510K	**K111207**	**K111207**		**K023836**
Company Name	**Respire Medical LLC**	**Respire Medical LLC**	**Respire Medical LLC**	**Strong Dental Inc.**
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)
Device Name	Device, Anti-Snoring	Device, Anti-Snoring	Device, Anti-Snoring	Device, Anti-Snoring
Product Code	LRK	LRK	LRK	LRK

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Classification	Class II	Class II	Class II	Class II
Intended Use	The Respire Blue Series is indicated to treat mild to moderate OSA.	The Respire Blue Series is indicated to treat mild to moderate OSA.	The Respire Pink Series - Herbst is indicated to treat mild to moderate OSA.	A custom fitted mandibular repositioning device intended to reduce or alleviated nighttime snoring and obstructive sleep apnea
Single or Multiple use	Multiple use	Multiple use	Multiple use	Multiple use
Target population	Adults Patients	Adults Patients	Adults Patients	Adults Patients
Prescription / OTC Use	Prescription only	Prescription only	Prescription only	Prescription only
Device Components	Orthodontic Acrylic trays, Expansion Screws, Wire with Ball Clasp	Orthodontic Acrylic trays, Expansion Screws, Wire with Ball Clasp	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp
Appliance Design	Customized device Rigid tray two pieces Upper/Lower acrylic	Customized device Rigid tray two pieces Upper/Lower acrylic	Customized device Rigid tray two pieces Upper/Lower acrylic	Customized device Rigid tray two pieces Upper/Lower acrylic
Device Functionality	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.
Mandibular Advancement range	Up to 6 mm	Up to 6 mm	Up to 8 mm	Up to 8 mm
Raw Material: Upper and Lower Trays	Acrylic (polyethyleneterephthalate)	Acrylic (polyethyleneterephthalate)	Acrylic (polyethyleneterephthalate)	Acrylic (polyethyleneterephthalate)
Raw Material: Metal Components	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Colorants	Red/Blue	Red/Blue	Pink	No colorant

Summary of Equivalence: The Respire Pink Series - Herbst is considered to be substantially equivalent to Respire Blue Series K111207 ; SUAD K023836 in terms of intended use, indication for use, technological characteristics, performance and user interface.

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As similar to its predicate device Respire Pink Series is a customized device, consists of two parts, upper and lower trays, made of acrylic. The difference between the Respire Blue Series and the Respire Pink Series is related to the hardware/components that are used on the buccal aspect to hold the lower jaw in a forward position.

The differences between Respire Pink Series – Herbst to SUAD appliance is that Respire Pink acrylic contour is designed to increase tongue space which is more comfortable for patient use. Respire Pink appliance is adjustable using titration keys and a screw which enables the jaw to be brought forward in small advancements. The design differences emphasis the advantages of Respire Pink Series technology and thus, raise no new safety and/or effectiveness issues. Respire Pink Series shares the same technological characteristics as its predicate devices and raise no new issues of safety or effectiveness, thus, the Respire Pink Series is substantially equivalent to its predicate devices.

Risk Assessment performance has demonstrated no new safety and/or effectiveness issues.

Bench testing results have demonstrated that all test method acceptance criteria were met and demonstrated equivalent results to the predicated devices. Thus, Respire Pink Series shares similarity with its predicate devices and raise no new safety and/or effectiveness issues.

Clinical testing - Clinical evaluation and observation results have demonstrated the success rate of reduction of snoring and the success rate of reduction of apneic events measured by polysomnograms. Thus, Respire Pink Series shares similarity in the indication of use and raise no new safety and/or effectiveness issues.

<u>Conclusion:</u>

As verified by clinical and non clinical data, bench testing and substantial equivalence table, Respire Pink Series shares similarity with its predicated device by term of intended use, raw material and technical design. The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices, thus Respire Pink Series is as safe and effective for its intended use and performs as well the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 9, 2013

Respire Medical Limited Liability Company
C/O Ms. Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22817 Ventura Boulevard #161
WOODLAND HILLS CA 91364

Re: K131138
Trade/Device Name: Respire Pink Series-Herbst
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: August 4, 2013
Received: August 9, 2013

Dear Ms. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4 - Indication for Use Statement

Indications for Use

Indications for Use

510(k) Number (if known): K131138

Device Name:

Respire Pink Series - Herbst

Indications for Use:

The Respire Pink Series - Herbst is indicated to treat mild to moderate OSA.

Prescription Use _✓__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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'Division Sign-Off)
'ision of Anesthesiology, General Hospital
ction Control, Dental Devices

10(k) Number: K131138

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